PATENT COOPERATION TREATY

PCT/JP2004/018430
EP

From the INTERNATIONAL BUREAU FITZ, AU, CA

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

KYOWA HAKKO KOGYO CO., LTD.
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Date of mailing *(day/month/year)* 03 August 2006 (03.08.2006)	
Applicant's or agent's file reference 1638	**IMPORTANT NOTIFICATION**
International application No. PCT/JP2004/018430	International filing date *(day/month/year)* 03 December 2004 (03.12.2004)
Applicant KYOWA HAKKO KOGYO CO., LTD. et al	

1. **Transmittal of the translation to the applicant.**

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 1638	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2004/018430	International filing date *(day/month/year)* 03 December 2004 (03.12.2004)	Priority date *(day/month/year)* 04 December 2003 (04.12.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 24 July 2006 (24.07.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 1638	Date of mailing *(day/month/year)* **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/018430	03.12.2004	04.12.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant
KYOWA HAKKO KOGYO CO., LTD.

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/018430

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/018430

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-26	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO

2. Citations and explanations:

<Documents referred to in the ISR>
Document 1: WO, 2003/018635, A1 (Kyowa Hakko Kogyo Co., Ltd.), 06 March, 2003 (06.03.03)
Document 2: WO, 2001/064754, A1 (Kyowa Hakko Kogyo Co., Ltd.), 07 September, 2001 (07.09.01)
Document 3: JP, 2002-539079, A (Millennium Pharmaceuticals Incorporated), 19 November, 2002 (19.11.02)
Document 4: TAKEUCHI, Hitoshi, Chemical Therapy for adult ALL, -Progress of Medical Science, 31 July, 1999 (31.07.99), Vol.1 190, No.5, p. 474-479
Document 5: OHNISHI, Kazunari, Standard Therapy of CML-Progress of Medical Science, 31 July, 1999 (31.07.99), Vol.190, No. 5, p. 481-485
Document 6: KUSUMOTO, Shuuya, et al, Usage of cytokine at therapy of acute leukemia-Progress of Medical Science, 31 July, 1999 (31.07.99), Vol. 190, No.5, p.522-529
Document 7: WO, 2002/010743, A1 (Ortho-Mcneil Pharmaceutical, Inc.) 07 February, 2002 (07.02.02)
Document 8: JP, 2002-544173, A (IMMUNOMEDICS INC.), 24 December, 2002 (24.12.02)
Document 9: WO, 2002/012347, A1 (IMMUNOMEDICS INC.), 14 February, 2002 (14.02.02)

<Explanation>
The inventions described in claims 1-26 do not appear to involve an inventive step in view of documents 1-9 referred to in the ISR.

Documents 1-3 describe a genetically modified antibody or its fragment bonded specifically to an extra-cellular region of human CC chemokine receptor 4 (CCR4), and describe its use as a curative medicine of blood cancers such as of leukemia and lymphoma.

Also, as described in documents 4-9, chemotherapy drugs such as G-CSF, interfelon-α, cytokines like IL-2, vincrestine, cyclophosphamide, etoposide and methotrexate are used generally as anti-tumor cures against tumors of hematopoietic organs, and anti-tumor drugs are generally medicated in concomitant use of multiple compositions.

In connection with medical supplies, it is generally practiced for a person skilled in the art to select and determine, as required, kinds of antibodies and combined drugs depending on the purpose, and it is found that a person skilled in the art can easily combine other drugs which contain a genetically modified antibody and its fragment bonded specifically to the extra-cellular region of a human CC chemokine receptor (CCR4) as described in documents 1-3, and further can conceive an invention by identifying antibodies and combined drugs to be specifically used.